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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	[REDACTED]

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JL

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No. 09/436,164	Applicant(s) Reubinoff, B. E.
	Examiner Joseph Woitach	Art Unit 1632
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<p>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</p> <p>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</p> <p>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</p> <p>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</p> <p>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p>		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Sep 30, 2002</u>		
2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-18, 20-26, 29-36, and 38-46</u> is/are pending in the application.		
4a) Of the above, claim(s) <u>1-18, 29-36, 45, and 46</u> is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>20-26 and 38-44</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p>		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. <p style="margin-left: 20px;">If approved, corrected drawings are required in reply to this Office action.</p>		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). <p>a) <input checked="" type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p>		
1. <input checked="" type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 		
<p>*See the attached detailed Office action for a list of the certified copies not received.</p>		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). <p>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p>		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>21</u> .		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____		

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 30, 2002, paper number 19, has been entered.

DETAILED ACTION

This application is an original application filed November 9, 1999 which claims benefit of foreign applications PP7009, filed November 9, 1998, and PQ2852, filed September 15, 1999, both filed in Australia.

Applicants amendment filed September 30, 2002, paper number 20 has been received and entered. Claims 19 and 37 have been canceled. Claims 20-26 and 38-44 have been amended. Claims 1-18, 20-26, 29-36, 38-46 are pending.

Election/Restriction

Applicant's election with traverse of groups II, claims 19-28, in Paper No. 10 was acknowledged. Applicants have not provided any new arguments to traverse the restriction

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requirement in the instant amendment. Therefore, for the reasons of record, the requirement is still deemed proper and is therefore made FINAL (see final rejection mailed May 22, 2002, paper number 15).

This application contains claims which are drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-18, 20-26, 29-36, 38-46 are pending, claims 1-18, 29-36, 45 and 46 are withdrawn from consideration as being drawn to a non-elected invention, and claims 20-26 and 38-44 are currently under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 20-26 and 38-44 stand rejected under 35 U.S.C. 102(b) as being anticipate by Thomson *et al.* (Science 282:1145-1147).

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Applicants note the amendment to the pending claims noting the specific conditions recited in the claims. Applicants argue that the methods taught by Thomson *et al.* do not point to the importance of feeder cells for the differentiation of ES cells. Moreover, it is noted that the methods taught by Thomson *et al.* are for the spontaneous differentiation, not the specific induction of differentiation which is encompassed by the instant claims. See Applicants' amendment, pages 6-7. Applicants' arguments have been fully considered but not found persuasive.

First, it is noted that Thomson *et al.* do teach the importance of feeder cells for the state of differentiation of human and primate cells. Unlike mouse ES cells, Thomson *et al.* teach that feeder cells are a requirement for maintaining the undifferentiated state of the ES cells. Further, the use of various sources of fibroblast cells, mouse versus human, is discussed with regard to their ability to serve as appropriate feeder cells for primate and human ES cells. Applicant's arguments that Thomson *et al.* only teach the spontaneous differentiation of ES cell not the specific induction of differentiation is not persuasive because Thomson *et al.* specifically teach the parameters to affect the differentiation of the cell lines was the feeder layer, the cell density, and various growth factors such as allowing the cells to proliferate without LIF. More specifically conditions wherein the ES cells are allowed to grow at high density it is known that differentiation of the ES cells will occur. It is noted that the present claims do not recite an method steps which are different from those disclosed by Thomson *et al.* In fact, the method to induce differentiation by culturing cells at high density is specifically recited in pending claim 25

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and 43. Applicants arguments that the instantly claimed methods are different from those disclosed by Thomson *et al.* are unpersuasive, because Thomson *et al.* teach the importance of the feeder cells and provide *in vitro* conditions which induce the cells to differentiate. Examiner acknowledges that the differentiation could be viewed as spontaneous to the extent that the specific factors which induce the cells to differentiate are not specifically known, however neither the instant claims nor the present specification teach these unknown factors. Clearly Thomson *et al.* teach the same method steps set forth in the claims and teach the importance of the feeder cells to the differentiation state of the ES cells. Therefore, for the reasons above and of record, the rejection is maintained.

Claims 20-26 and 38-44 stand rejected under 35 U.S.C. 102(e) as being anticipate by Thomson (US Patent 6,200,806).

Applicants note the amendment to the pending claims noting the specific conditions recited in the claims. Applicants argue that the methods taught by Thomson *et al.* do not point to the importance of feeder cells for the differentiation of ES cells. Moreover, it is noted that the methods taught by Thomson *et al.* are for the spontaneous differentiation, not the specific induction of differentiation which is encompassed by the instant claims. Additionally, Applicants argue that Thomson *et al.* only teaches extraembryonic differentiation not somatic differentiation as required by the instant claims. See Applicants' amendment, pages 7-8. Applicants' arguments have been fully considered but not found persuasive.

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As noted above, Thomson *et al.* do teach the importance of feeder cells for the state of differentiation of human and primate cells. Thomson *et al.* teach that feeder cells are a requirement for maintaining the undifferentiated state of the ES cells. Applicants arguments that Thomson *et al.* only teach the spontaneous differentiation of ES cell not the specific induction of differentiation is not persuasive because Thomson *et al.* specifically teach the parameters to affect the differentiation of the cell lines was the feeder layer, the cell density, and various growth factors. Applicants' arguments that the cells produced by Thomson *et al.* are only extraembryonic while the present claims are drawn to somatic cells is unpersuasive because the instantly claimed methods are the same as those disclosed by Thomson *et al.* the present claims do not recite any method steps which are different from those disclosed by Thomson *et al.* The specific conditions wherein the ES cells are allowed to grow at high density is known to induce differentiation of the ES cells the same method to induce differentiation by culturing cells at high density is specifically recited in pending claim 25 and 43. Applicants arguments that the instantly claimed methods are different from those disclosed by Thomson *et al.* are unpersuasive, because Thomson *et al.* teach the importance of the feeder cells and provide *in vitro* conditions which induce the cells to differentiate. Examiner acknowledges that the differentiation could be viewed as spontaneous to the extent that the specific factors which induce the cells to differentiate are not specifically known, however neither the instant claims nor the present specification teach these unknown factors. Clearly Thomson *et al.* teach the same method steps

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set forth in the claims and teach the importance of the feeder cells to the differentiation state of the ES cells. Therefore, for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


RAM R. SHUKLA, PH.D
PATENT EXAMINER